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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,685	10/06/2005	Heinz Winkler	WBW-13116	8378

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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,685	WINKLER, HEINZ	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-38* is/are pending in the application.

4a) Of the above claim(s) *25-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response of 10/23/2008 has been received and entered into the application file. Claims 13-15, 18, 19, 21 and 25 have been amended. Claims 13-38 remain pending in the current application, of which claims 25-38 remain withdrawn pursuant to 37 CFR 1.142(b), as being directed to a non-elected invention. Election was made **without** traverse in the response of 2/7/2008.

It is noted Applicants have not provided claims 25-38 with the proper status identifier ("withdrawn" or "withdrawn-amended"), as required by 37 CFR 1.121(c), and thus the amendment may be considered non-compliant; however in order to provide compact prosecution the amendment will be entered, but future responses must be in accordance with 37 CFR 1.121(c).

Claims 13-24 have been considered on the merits. Applicant's arguments have been fully considered and are each addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file. The instant application is a national stage entry of PCT/AT03/00362, filed 12/05/2003. Additionally, acknowledgment is made of applicant's claim for foreign priority under 35 USC 119(a)-(d) to Austrian application 1825/2002, filed 12/05/2002. A certified copy of the foreign priority document has been received and placed in the application file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-25 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, as amended, is considered indefinite.

First, it is unclear how the amendment is intended to define the composition of the supporting body. It is not clear if the supporting body must *consist of* bone of human or animal origin in an unaltered state (which would conflict with at least claim 24), if the supporting body must *consist of* elements of or derived from bone of human or animal origin (*i.e.* collagen, hydroxyapatite, demineralized bone matrix, bone gelatin, etc), if the supporting body must *comprise* bone of human or animal origin in an unaltered state, or if the supporting body must *comprise* elements of or derived from bone of human or animal origin. Clarification is required.

Second, it is unclear what is meant by the phrase "a supporting body of a bone of human or animal origin *and forming a body-tolerable* material having a porous or spongy structure" (emphasis added). It is not clear if the language is intended to state the supporting body *is* a body-tolerable material (*i.e.* "and *forms* a body-tolerable material), or if some manipulation must be carried out on the supporting body of human or animal bone to form it into a body tolerable material. Clarification is required.

In claim 13, the phrase "tissue cell suspension" remains unclear. A tissue is an aggregate of interconnected cells with intracellular connections, *i.e.* not a suspension of cells. Dependent claims 14-24 inherit the deficiency of claim 13, and therefore are rejected on the same basis. Clarification is required.

Claim 15 has been amended to recite that the supporting body is impregnated with a cartilage tissue cell suspension containing individual cells of a cartilage tissue. First the language is considered awkward, it would be remedial to refer to the supporting body being impregnated simply with a

suspension of cells from a cartilage tissue. Second, claim 13, as amended requires the supporting body to be impregnated with a 'tissue cell suspension', it is not clear if the tissue cell suspension containing individual cells of a cartilage tissue, recited in claim 15, is the same 'tissue cell suspension' as recited in claim 13, or a different 'tissue cell suspension'. Clarification is required.

Claim 24 still lacks antecedent basis for the limitation "the part of said supporting body impregnated with cartilage cell suspension" in the 1st-2nd lines of the claims. It is noted claim 24 now depends from claim 15, which recites "said supporting body is impregnated with a cartilage tissue cell suspension", however claim 15 still does not refer to a *part* of the supporting body being impregnated with a cell suspension, and thus antecedent basis is still lacking. The term "part" infers a portion of the whole (**part:1 a** (1)**:** one of the often indefinite or unequal subdivisions into which something is or is regarded as divided and which together constitute the whole, from Merriam-Webster Online Dictionary, URL: http://m-w.com/dictionary/part, retrieved 12/25/2008). Claim 15 does not state a "part" of the supporting body being impregnated, but rather only states "said supporting body" (interpreted as referring to the whole supporting body) is impregnated. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 14 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment to claim 14 introduces a negative limitation, specifically claim 14 defines the supporting body as a *non-engineered* piece of a spongy bone of human or animal origin, however there is insufficient support for this negative limitations and it is therefore being considered new matter. An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989).

The specification, as originally filed, discloses the supporting body is preferably a piece of spongy bone of human or animal origin (See Specification, *e.g.* Pg. 1, ln 6-11); however the specification does not define the spongy bone of human or animal origin as being *non-engineered*. Therefore, there is not sufficient support in the specification, as originally filed, to support the negative limitation. While Applicants may limit the material of the supporting body by defining the precise materials, there is insufficient support to define the material by *excluding* particular embodiments (*i.e.* non-engineered). Applicant is required to cancel the new matter in the reply to this Office Action.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The subject matter of original claims 3 and 4 (from National stage filing of 6/6/2005) is not present in the original specification. The limitations found in original claims 3 and 4 are necessary to provide written description for current claims 13-24. Specifically:

(i) original claim 3 defines the infiltrating channels as having a hollow cylindrical shape with a diameter in the range of 300 to 500 um. Such a limitation (particularly hollow cylindrical infiltrating channels) is not in the specification, but is recited in current claim 16.

(ii) original claim 3 defines the infiltrating channels as having a tapering pointed cone or pointed conical or pointed frustum-like shape in the direction of the interior of the supporting body, each having a

diameter in the center of 200 to 500 um. Such a limitation (particularly a center diameter of 200 to 500 um) is not in the specification, but is recited in current claims 19-21.

(iii) original claim 4 defines the infiltrating channels has having a depth that is 3 to 10 fold, particularly 5 to 10 fold, greater than the center diameter. Such a limitation is not in the specification, but is recited in current claims 17, 18 and 21.

Because the original claims are considered part of the original disclosure, current claims 16-21 are not rejected as lacking written description in the disclosure as originally filed for the particular limitations discussed above; however Applicants must amend the specification to include the claimed subject matter, as provided in original claims 3 and 4. See *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Applicants have traversed the rejection of record based on Beam et al, on the grounds that Beam et al disclose use of a synthetic matrix produced from bone particles and which has a uniform porous structure, which Applicants assert is distinct from the supporting body in the claimed implant, which they assert is genuine bone particle material having natural bone structure (presumably referring to the trabeculae of spongy bone). Applicants assert the implant body of the instant invention is natural bone

pieces of spongy bone, which is not comminuted, bonded or shaped, and thus retains its natural bone structure in an unmodified way (See Response, paragraph spanning pages 11-12)

In response, it is respectfully submitted that Applicants are arguing limitations not in the presently examined claims, and thus the arguments are not persuasive to overturn the rejection of record.

First, as discussed above under the provisions of 35 USC 112, second paragraph, the claims do not clearly define the composition of the supporting body, thus Applicants' assertion that the claims define the implant material as *consisting of* un-modified natural spongy bone is not supported. In giving claim 13 its broadest reasonable interpretation, the supporting body must only comprise one or more compositional elements of bone of human or animal origin (such as hydroxyapatite, collagen, osteoblasts, etc, or elements which may be derived from bone, such as demineralized bone matrix, bone gelatin, etc). Therefore, because Beam et al do disclose their ERB may be made from hydroxyapatite and/or demineralized bone particles, the ERB of Beam et al still reads on the instant claim. It is further noted that the source of the hydroxyapatite (derived directly from bone, synthetically produced, or derived from a source other than bone) does not effect its chemical make-up, and thus the source of the supporting body material does not have an effect on the final implant.

Second, none of the claims provide for a limitation that the material of the supporting body must retain the natural bone structure of spongy bone, and thus must be natural bone tissue which has not been ground, bonded (processed) or subjected to a shaping process. Independent claim 13 only states the supporting body must have a porous or spongy structure, it does not require the structure must be that of natural, unaltered bone trabeculae. None of the claims state the material used for the supporting body cannot be ground, or processed. Only claim 14 presents a limitation excluding engineered bone, however grinding, bonding, and shaping natural *non-engineered* bone is still not excluded.

Therefore, claims 13 and 22 stand rejected under 35 U.S.C. 102(e) as being anticipated by Beam et al (US 2003/0065400).

Beam et al disclose an engineered regenerative biostructure (ERB) which useful as a bone implant material.

The ERB comprises a plurality of particles, the particles may be of a ceramic or inorganic substances, such as hydroxyapatite, tricalcium phosphate and other calcium phosphates, the particles may also include demineralized bone matrix (See Beam et al, paragraph 0046). Hydroxyapatite is a component of natural bone. Demineralized bone matrix is produced from natural bone. Therefore, wherein the ERB comprises particles of hydroxyapatite and/or demineralized bone matrix, the supporting body is considered to comprise elements of bone of human or animal origin which form a body-tolerable material.

The ERB exhibits a microporosity between packed particles, and it further has an engineered internal architecture, which may include micro-, meso- and/or macroporosity in the form of interconnected channels and/or pores (See Beam et al, at least paragraphs 0041, 0045-0046 & 0054-0057).

Various substances may be infused into the engineered internal architecture, including cells (which Applicants call a tissue cell suspension for regeneration) (See Beam et al, paragraphs 0041 & 0192).

The ERB of Beam et al is considered to read on the instantly claimed implant material, as the ERB is considered to be a supporting body of a body-tolerable material which includes elements of bone of human or animal origin, and which has a porous structure; furthermore, the engineered internal architecture, comprising micro-, meso-, and macroporosity, of the ERB is considered to read on infiltration channels which are capable of receiving a cell suspension therewithin for regeneration of bony tissue upon implantation (claim 13).

The shape of the ERB may be manipulated to fit the defect. Figure 2A shows an ERB (200) having a cylindrical shape, having a base and a top (which applicants call a 'cover surface'), wherein at least some of the infiltrating channels (220) start at the base of the ERB (See Beam et al, paragraph 0047 & Fig. 2A) (claim 22).

Therefore the reference anticipates the claimed subject matter.

Applicants have traversed the rejection of record based on Mears et al, on the grounds that Mears et al disclose use of synthetic polymers and metals as the material for the supporting body, which are not of bone origin, nor do they share any elements with bone.

In response, the amendment to the claims does differentiate over the teachings of Mears et al, as none of the components used by Mears et al share any compositional features with natural bone of human or animal origin. Therefore the rejection under 35 USC 102(b) over Mears et al is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicants have traversed the rejections of record based on Beam et al and Beam et al in view of Mears et al, on the grounds that Beam et al does not teach the implant of claim 13 for the reasons set forth above. Applicants do not separately address the holding of obviousness over claims 15-21, 23 and 24.

Applicants' arguments against Beam et al have been addressed in detail above, and will not be repeated for the sake of brevity herein.

Therefore claims 13 and 16-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Beam et al (US 2003/0065400).

The teachings of Beam et al are set forth above; Beam et al has been shown to anticipate claims 13 and 22. Generally Beam et al disclose an engineered regenerative biostructure (ERB) which useful as a bone implant material; the ERB is made of 'body-tolerable materials' which are from natural bone (demineralized bone matrix) or identical to elements found in bone (hydroxyapatite). The ERB exhibits a microporosity between packed granules, and it further has an engineered internal architecture, which may include micro-, meso- and/or macroporosity in the form of interconnected channels and/or pores (See Beam et al, at least paragraphs 0041, 0045-0046 & 0054-0057).

Beam et al differs from the instant invention in that they do not disclose the exact same shapes, sizes and orientations of the engineered internal architecture (considered to read on the infiltrating channels of the instant invention), nor do they disclose the ERB body to exhibit a cylindrical shape with one end having a convex shape. However, because the differences between Beam et al and the instant invention are limited to differences in size and shape, and Beam et al discloses the size and shape of both the internal architecture and the shape of the ERB body can each be manipulated to suit the individual design needs, the instant invention is considered to be *prima facie* obvious over Beam et al. It has been held that in situations where the only difference between the prior art and the claimed invention is a difference in shape or size, and the prior art discloses means for modifying the shape and/or size of their product in order to suit a design need, and there is otherwise no persuasive evidence that the claimed configuration was significant or that a device having the claimed relative dimensions would perform differently than the prior art device, the claimed product is not patentably distinct from the prior art product. See *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966),* and *In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).*

With regards to the dimensions of the engineered internal architecture (including the channels and pores), Beam et al disclose the micro-, meso- and/or macroporosity may be designed to form a predetermined pattern (See Beam et al, paragraphs 0054-0057 & 0073-0090, particularly 0083). Particularly with regards to 'macrochannels', Beam et al disclose the channels may have a dimension of 2 to 2000 microns, preferably from 200-700 microns (See Beam et al, paragraph 0056). Please note this range substantially overlaps that claimed (200-500 microns), it has been held that when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)*. The channels may be long in comparison to their width and/or depth. Beam et al further discloses the cross-section of the channels may be constant, or alternatively may be variable, thereby suggesting infiltrating macrochannels that start from the surface of the supporting body and taper inwardly, such as to a pointed cone shape or to a pointed frustum shape. Therefore, the size, shape and orientation of the infiltrating macrochannels in the ERB of Beam et al are considered to render obvious the infiltrating channels currently claimed (claims 16-21).

With regards to the shape of the ERB, Beam et al disclose the shape of the ERB may be manipulated to fit the defect. Figure 2A shows an ERB (200) having a cylindrical shape, having a base and a top (which applicants call a 'cover surface'), wherein at least some of the infiltrating channels (220) start at the base of the ERB (See Beam et al, paragraph 0047 & Fig. 2A). Figure 2A does not show the ERB to have a convex top (cover surface); however, because the shape of the ERB can be designed to specifically fit an anatomical defect (See Beam et al, paragraph 0047), manipulation of the ERB to have any desired shape, including that described in claim 23, would have been *prima facie* obvious to one of ordinary skill in the art (claim 23).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13, 15, 22 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Beam et al (US 2003/0065400), in view of Mears (US Patent 4,553,272).

The teachings of Beam et al are set forth above; Beam et al has been shown to anticipate claims 13 and 22. Generally Beam et al disclose an engineered regenerative biostructure (ERB) which useful as a bone implant material; the ERB is made of 'body-tolerable materials'. The ERB exhibits a microporosity between packed granules, and it further has an engineered internal architecture, which may include micro-, meso- and/or macroporosity in the form of interconnected channels and/or pores (See Beam et al, at least paragraphs 0041, 0045-0046 & 0054-0057).

Beam et al differs from the instant invention in that, while they state various substances may be infused into the engineered internal architecture (See Beam et al, paragraphs 0041 & 0192), they do not specifically disclose a cartilage cell suspension as such a material.

Mears discloses producing an implant material for regeneration of bony tissue, including joints, comprising introducing cartilage cells into a porous implant material (See Mears, col. 2, ln 15-39). Mears states the presence of cells within the porous implant advantageously aids in regeneration of natural tissue upon implantation (See Mears col. 4, ln 65-col. 5, ln 6).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to apply a cartilage cell suspension (as disclosed by Mears) to the ERB of Beam et al (claims 15, 24). One of ordinary skill would have been motivated to apply a cartilage cell suspension to the ERB of Beam et al in order to induce growth of cartilage cells (chondrocytes) within the ERB so that, upon implantation, the implant material will have a greater probability of successfully incorporating as a natural tissue structure. One would have had a reasonable expectation of successfully applying a cartilage

cell suspension to the ERB of Beam et al because Beam et al state various substances and biologic agents can be imbibed into the porous ERB, and Mears provides teachings on how to produce a cartilage cell suspension, and how to seed such a cell suspension onto porous implant materials. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13-24 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Sires (US Patent 5,112,354), in view of Mears (US Patent 4,553,272).

Sires discloses demineralized, textured, allogenic bone material for use in implantation.

The bone material is obtained from cadavers (human), and is not ground or comminuted, thus it retains the original porous or spongy structure of the trabeculae of bones (See Sires, abstract).

The bone material is texturized to increase surface area exposure. The bone material is texturized by producing pores and/or holes in the bone by means of mechanical drilling or a laser. Sires recites the size, density and depth of pores is selected to maximize the surface area of the implant while minimizing the loss of structural integrity. The pores may have a diameter between 200 and 2000 um, the depth of the pores may be varied depending on the shape of the bone graft section and the orientation of the pores, but may extend fully through the bone material. When the pores do not extend completely through the bone material, the pores may terminate in a tapered or conical configuration within the bone (See Sires, col. 3, ln 48-col. 5, ln 10).

The bone material is subsequently demineralized and subjected to further treatments prior to implantation (See Sires, col. 6, ln 6, ln 14-60 & claim 1).

The demineralized, textured, allogenic bone material of Sires is considered to read on a supporting body of a bone of human origin which forms a body-tolerable material having a porous and

spongy structure, representative of that of natural bone. Pores formed in the bone material read on the infiltration channels beginning from a surface and ending in the bone body. The size, shape and dimension of the original bone material, as well as the pores, has been reported as optimizable based on the desired implant location, defect size and shape, and the dimensions of the allogenic bone material (relevant to claims 13, 16-23). The bone of Sires is recovered from a cadaver, and thus is non-engineered (relevant to claim 14).

The bone material of Sires differs from the implant material of the instant invention in that it does not comprise a cell suspension in the pores or holes (infiltration channels). However, it is submitted that infiltrating an implant material intended for regeneration of tissues with a cell suspension increases the effectiveness of the implant in regenerating the tissue. In support, see Mears.

Mears discloses producing an implant material for regeneration of bony tissue, including joints, comprising introducing cartilage cells into a porous implant material (See Mears, col. 2, ln 15-39). Mears states the presence of cells within the porous implant advantageously aids in regeneration of natural tissue upon implantation (See Mears col. 4, ln 65-col. 5, ln 6).

Based on the teachings of Mears, one of ordinary skill in the art would have been motivated to include cells, including cartilage cells, as taught by Mears in the bone material of Sires, as the bone material of Sires may be used to replace any bony tissue, including joints, which have cartilaginous portions, for the predictable result of improving the regeneration of natural tissue upon implantation (Claims 13-24). One would have had a reasonable expectation of successfully applying a cartilage cell suspension to the bone material of Sires because the bone material of Sires is porous, both naturally due to the bone structure, and due to the presence of the pores and holes, and because Mears provides teachings on how to produce a cartilage cell suspension, and how to seed such a cell suspension onto

porous implant materials. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651